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Russo et al.

[11] Patent Number: 6,135,949

[45] Date of Patent: Oct. 24, 2000

[54] **APPARATUS FOR MONITORING AND/OR CONTROLLING A MEDICAL DEVICE**

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[21] Appl. No.: **09/152,573**

[22] Filed: **Sep. 14, 1998**

Related U.S. Application Data

[63] Continuation of application No. 08/691,872, Aug. 2, 1996, Pat. No. 5,807,336.

[51] **Int. Cl.**[7] **A61B 5/00**

[52] **U.S. Cl.** **600/300**; 604/131

[58] **Field of Search** 600/300; 604/207, 604/246, 131; 607/60; 128/904

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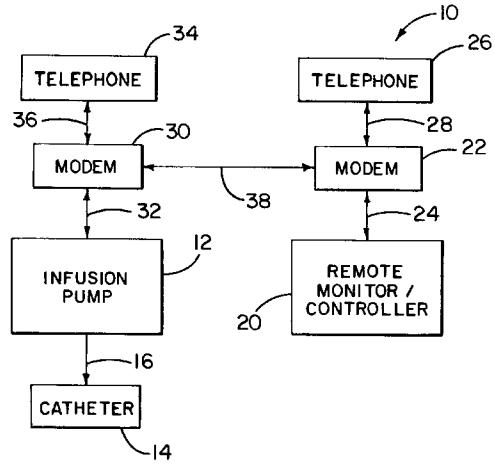
[57] **ABSTRACT**

A medical apparatus is provided with a programmable medical device disposed at a first room location and a remote monitor and/or controller disposed at a second room location. The programmable medical device is used to administer a medical treatment to a patient, and the remote monitor/controller may be used to monitor the operation of the medical device, control the operation of the medical device, and/or to transfer data from the medical device to the remote monitor/controller. The apparatus may allow voice communication between the remote monitor/controller and the patient who is receiving treatment via the medical device while the medical device is being monitored and/or controlled from the remote location. The remote monitor/controller may also include means for determining the type of medical device to which it is connected.

9 Claims, 12 Drawing Sheets



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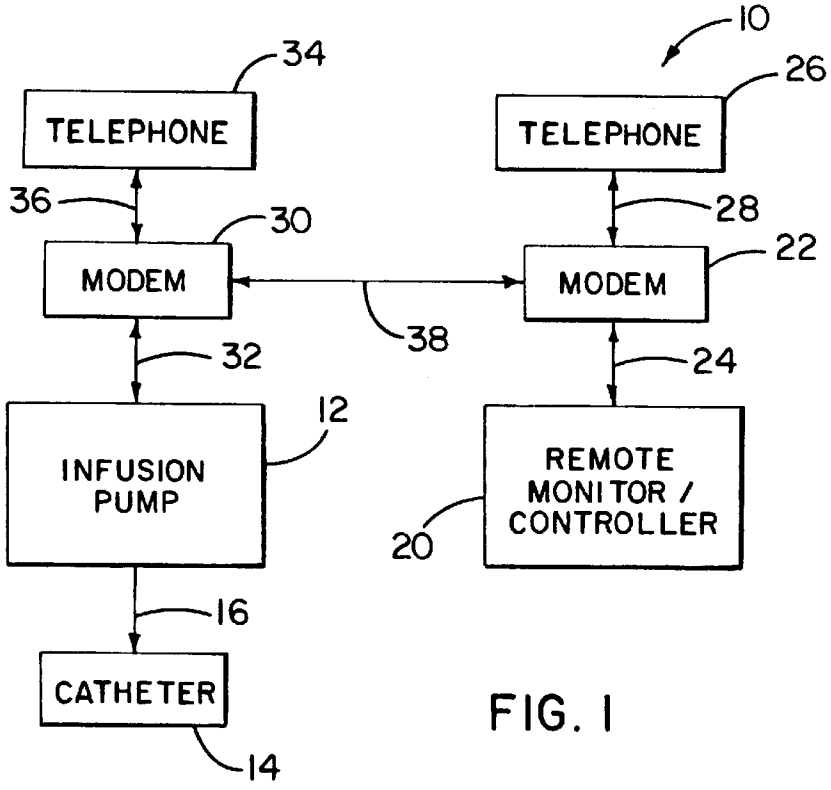

10
34
TELEPHONE
26
TELEPHONE
36
30
28
MODEM
22
MODEM
38
32
24
12
INFUSION PUMP
REMOTE MONITOR / CONTROLLER
20
16
CATHETER
14

FIG. 1

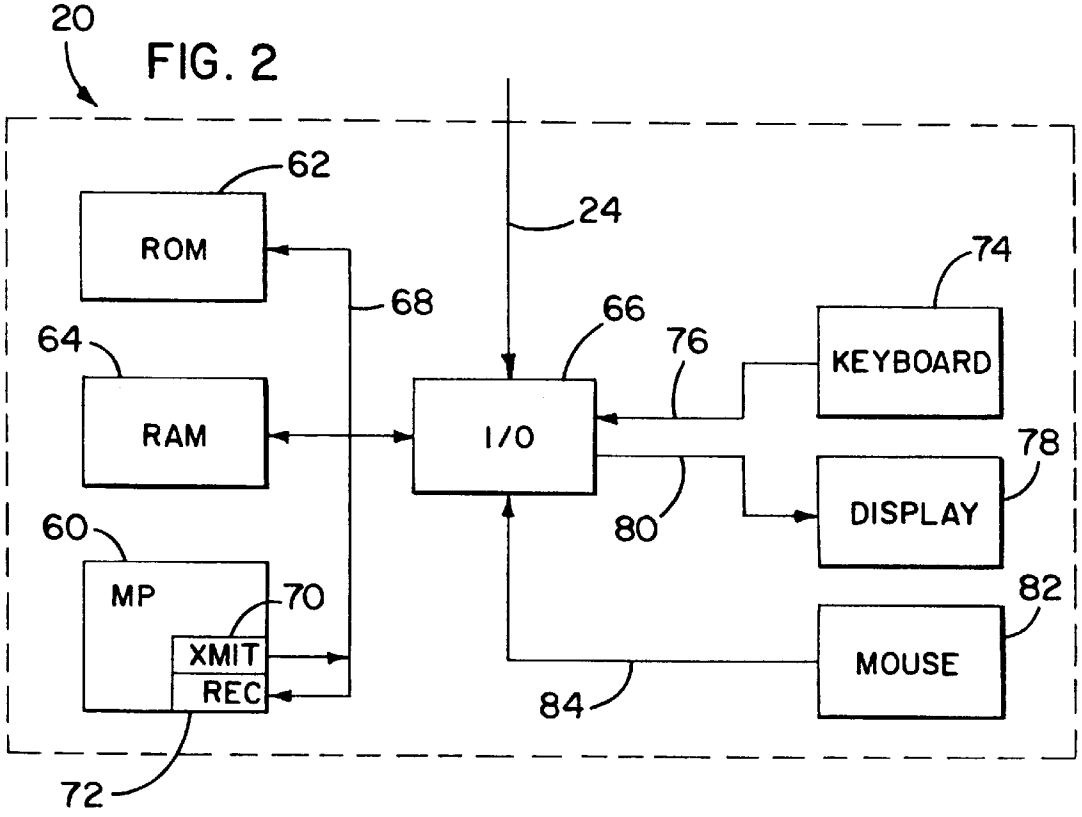

20
62
ROM
24
74
68
66
64
76
KEYBOARD
RAM
I/O
78
80
DISPLAY
60
MP
70
82
XMIT
REC
MOUSE
84
72

FIG. 2

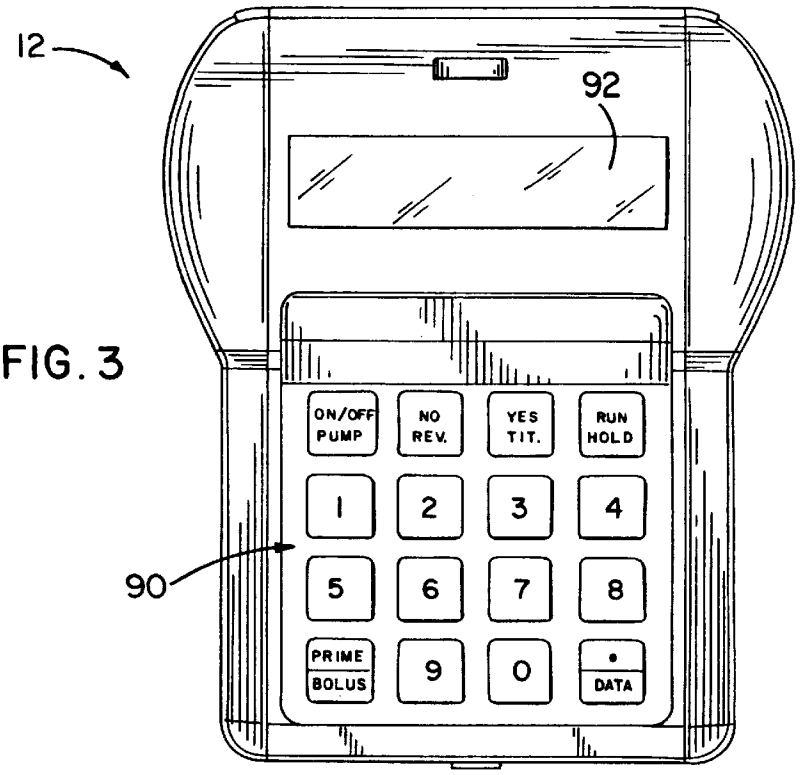

12
92
ON/OFF PUMP
NO REV.
YES TIT.
RUN HOLD
1
2
3
4
5
6
7
8
PRIME BOLUS
9
0
• DATA
90

FIG. 3

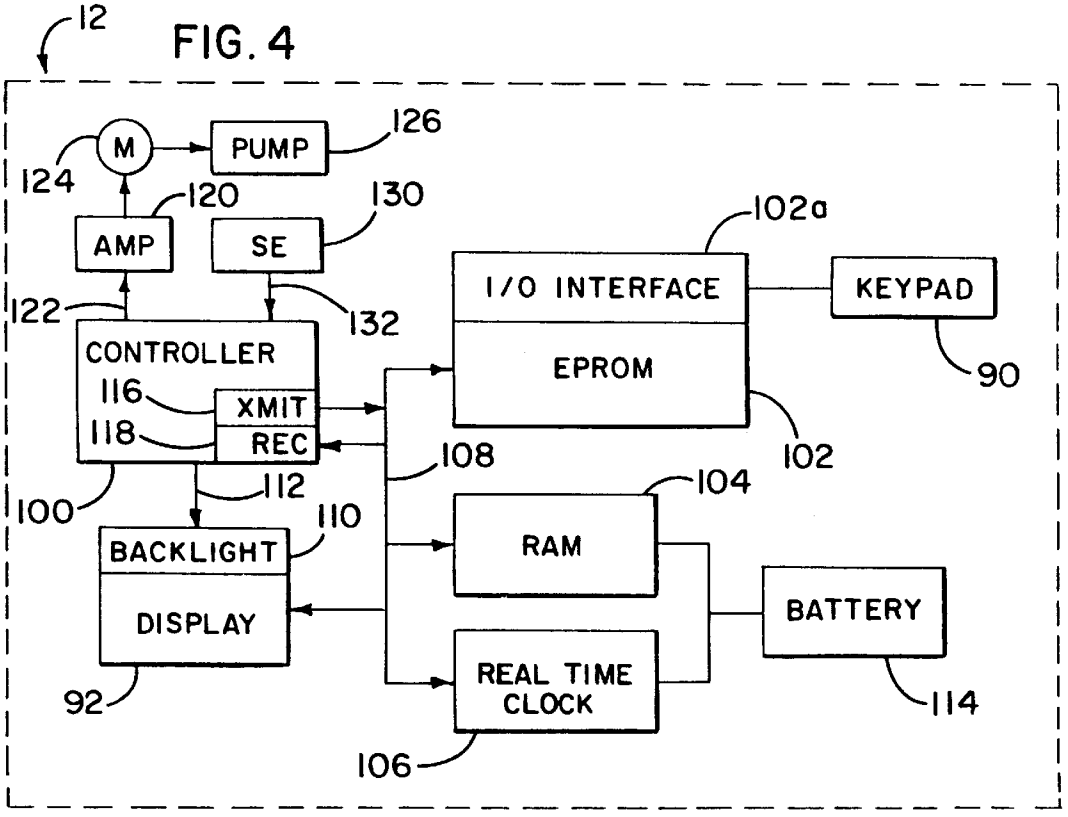

12
M
PUMP
126
124
120
130
AMP
SE
102a
I/O INTERFACE
KEYPAD
122
132
CONTROLLER
EPROM
90
116
XMIT
118
REC
108
102
100
112
104
110
BACKLIGHT
RAM
DISPLAY
BATTERY
92
REAL TIME CLOCK
114
106

FIG. 4

FIG. 5

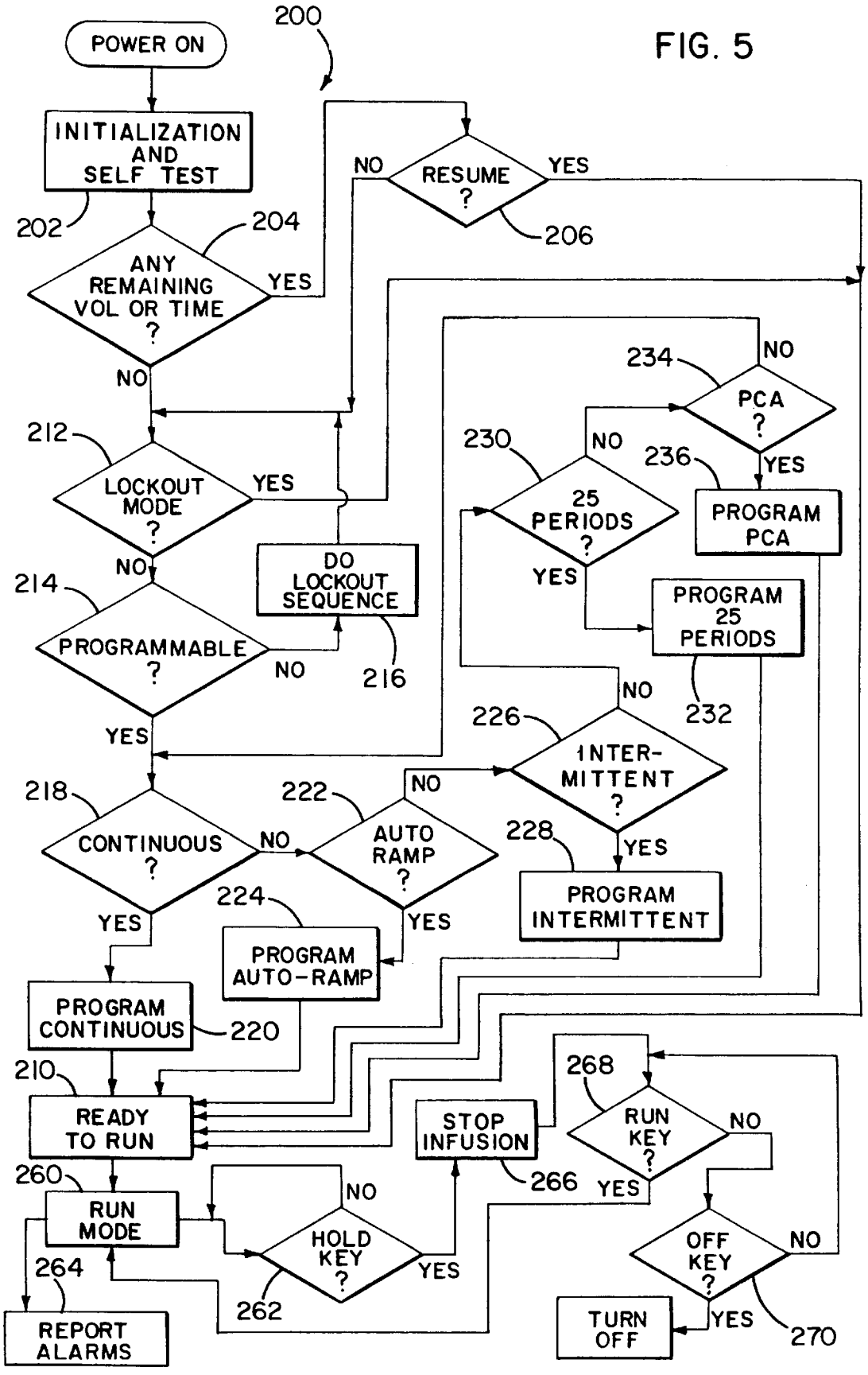
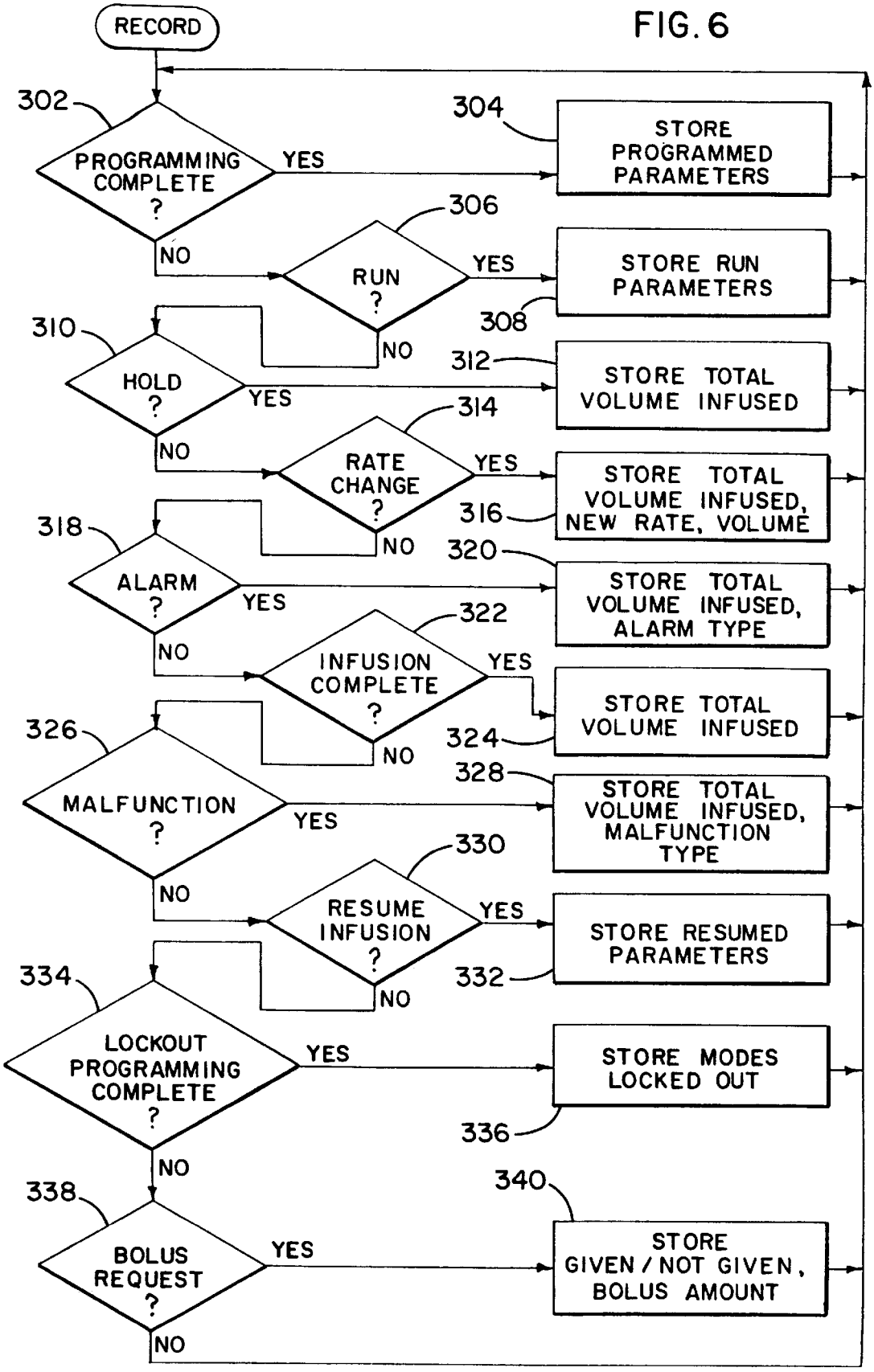

200
POWER ON
INITIALIZATION AND SELF TEST
202
RESUME ?
NO
YES
206
204
ANY REMAINING VOL OR TIME ?
YES
NO
234
NO
PCA ?
YES
236
212
LOCKOUT MODE ?
YES
230
NO
25 PERIODS ?
YES
PROGRAM PCA
NO
DO LOCKOUT SEQUENCE
214
PROGRAMMABLE ?
NO
216
PROGRAM 25 PERIODS
232
NO
226
INTER-MITTENT ?
YES
228
YES
218
CONTINUOUS ?
NO
222
AUTO RAMP ?
NO
YES
224
PROGRAM INTERMITTENT
YES
PROGRAM AUTO-RAMP
PROGRAM CONTINUOUS
220
210
READY TO RUN
268
RUN KEY ?
NO
YES
STOP INFUSION
266
260
RUN MODE
NO
HOLD KEY ?
YES
262
OFF KEY ?
NO
YES
270
264
REPORT ALARMS
TURN OFF

FIG. 6


RECORD
302
PROGRAMMING COMPLETE ?
YES
304
STORE PROGRAMMED PARAMETERS
NO
306
RUN ?
YES
STORE RUN PARAMETERS
308
NO
310
HOLD ?
YES
312
STORE TOTAL VOLUME INFUSED
NO
314
RATE CHANGE ?
YES
STORE TOTAL VOLUME INFUSED, NEW RATE, VOLUME
316
NO
318
ALARM ?
YES
320
STORE TOTAL VOLUME INFUSED, ALARM TYPE
NO
322
INFUSION COMPLETE ?
YES
STORE TOTAL VOLUME INFUSED
324
NO
326
MALFUNCTION ?
YES
328
STORE TOTAL VOLUME INFUSED, MALFUNCTION TYPE
NO
330
RESUME INFUSION ?
YES
STORE RESUMED PARAMETERS
332
NO
334
LOCKOUT PROGRAMMING COMPLETE ?
YES
STORE MODES LOCKED OUT
336
NO
338
BOLUS REQUEST ?
YES
340
STORE GIVEN / NOT GIVEN, BOLUS AMOUNT
NO

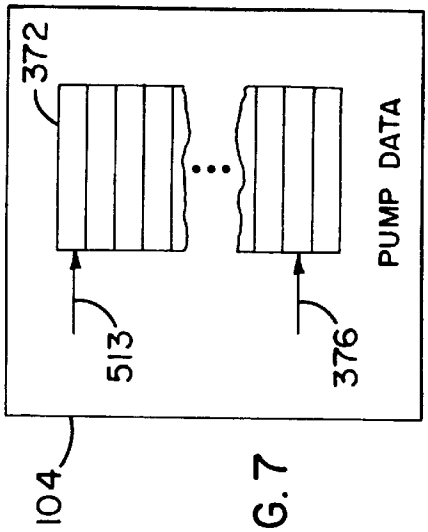

372
513
376
PUMP DATA
104

FIG. 7

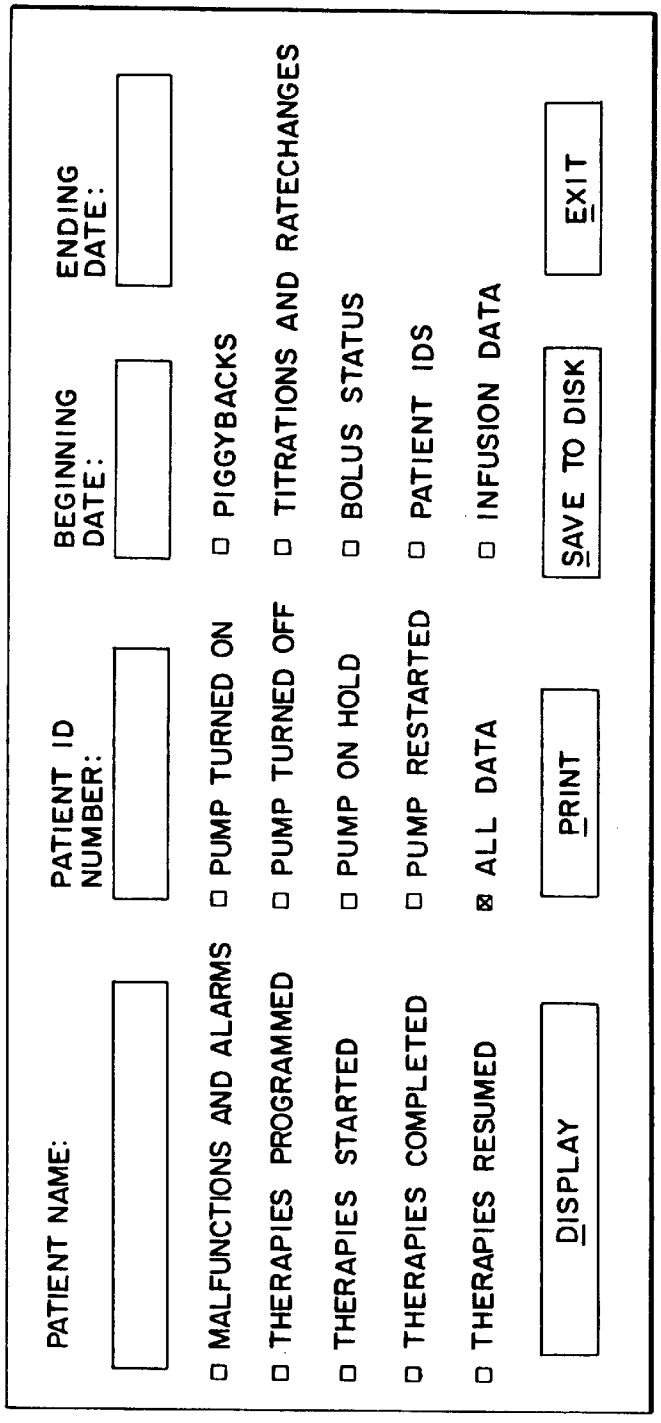

PATIENT NAME:
PATIENT ID NUMBER:
BEGINNING DATE:
ENDING DATE:
☐ MALFUNCTIONS AND ALARMS
☐ PUMP TURNED ON
☐ PIGGYBACKS
☐ THERAPIES PROGRAMMED
☐ PUMP TURNED OFF
☐ TITRATIONS AND RATECHANGES
☐ THERAPIES STARTED
☐ PUMP ON HOLD
☐ BOLUS STATUS
☐ THERAPIES COMPLETED
☐ PUMP RESTARTED
☐ PATIENT IDS
☐ THERAPIES RESUMED
☒ ALL DATA
☐ INFUSION DATA
DISPLAY
PRINT
SAVE TO DISK
EXIT

FIG. 15

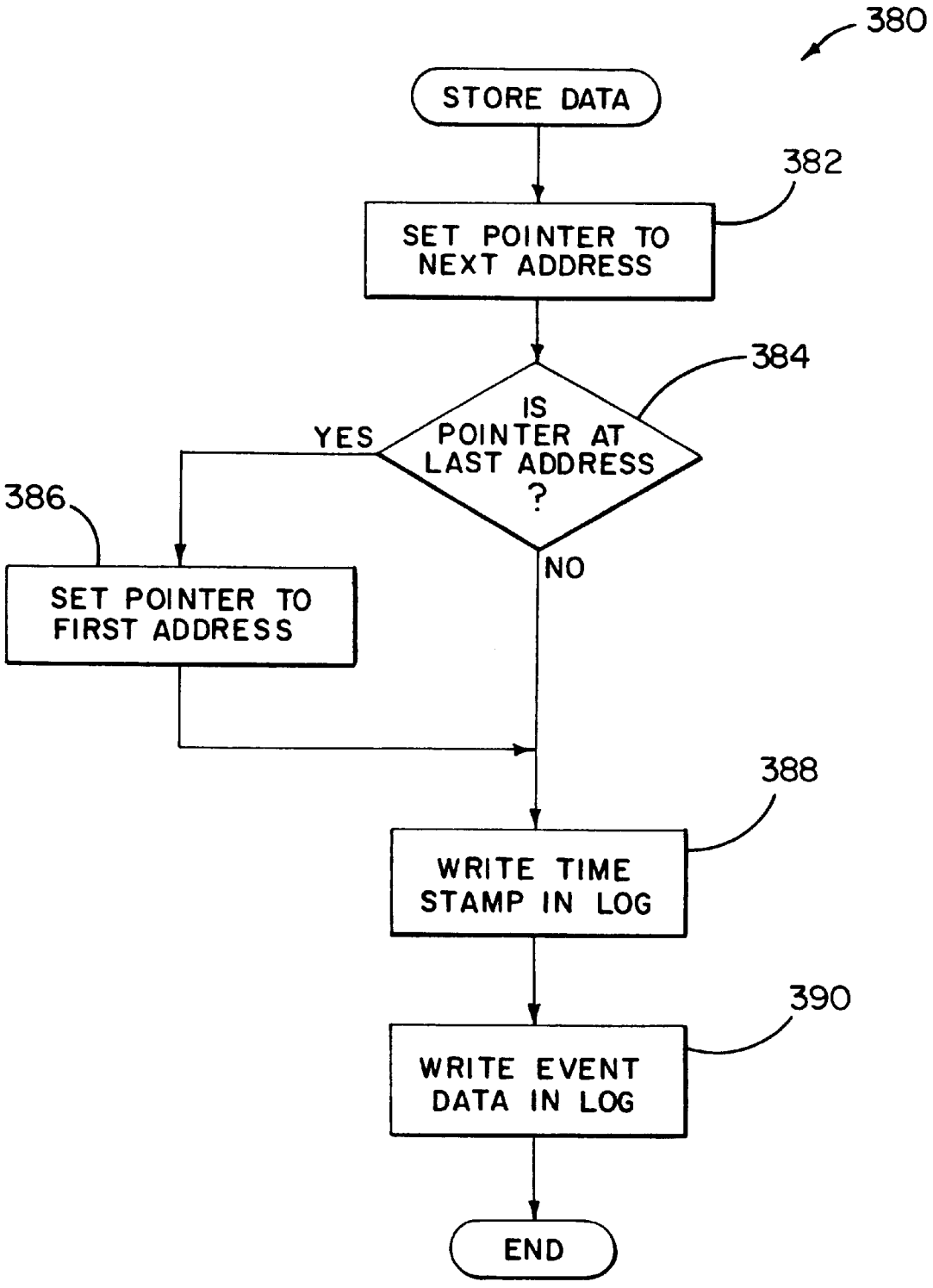

380
STORE DATA
382
SET POINTER TO NEXT ADDRESS
384
IS POINTER AT LAST ADDRESS ?
YES
NO
386
SET POINTER TO FIRST ADDRESS
388
WRITE TIME STAMP IN LOG
390
WRITE EVENT DATA IN LOG
END

FIG. 8

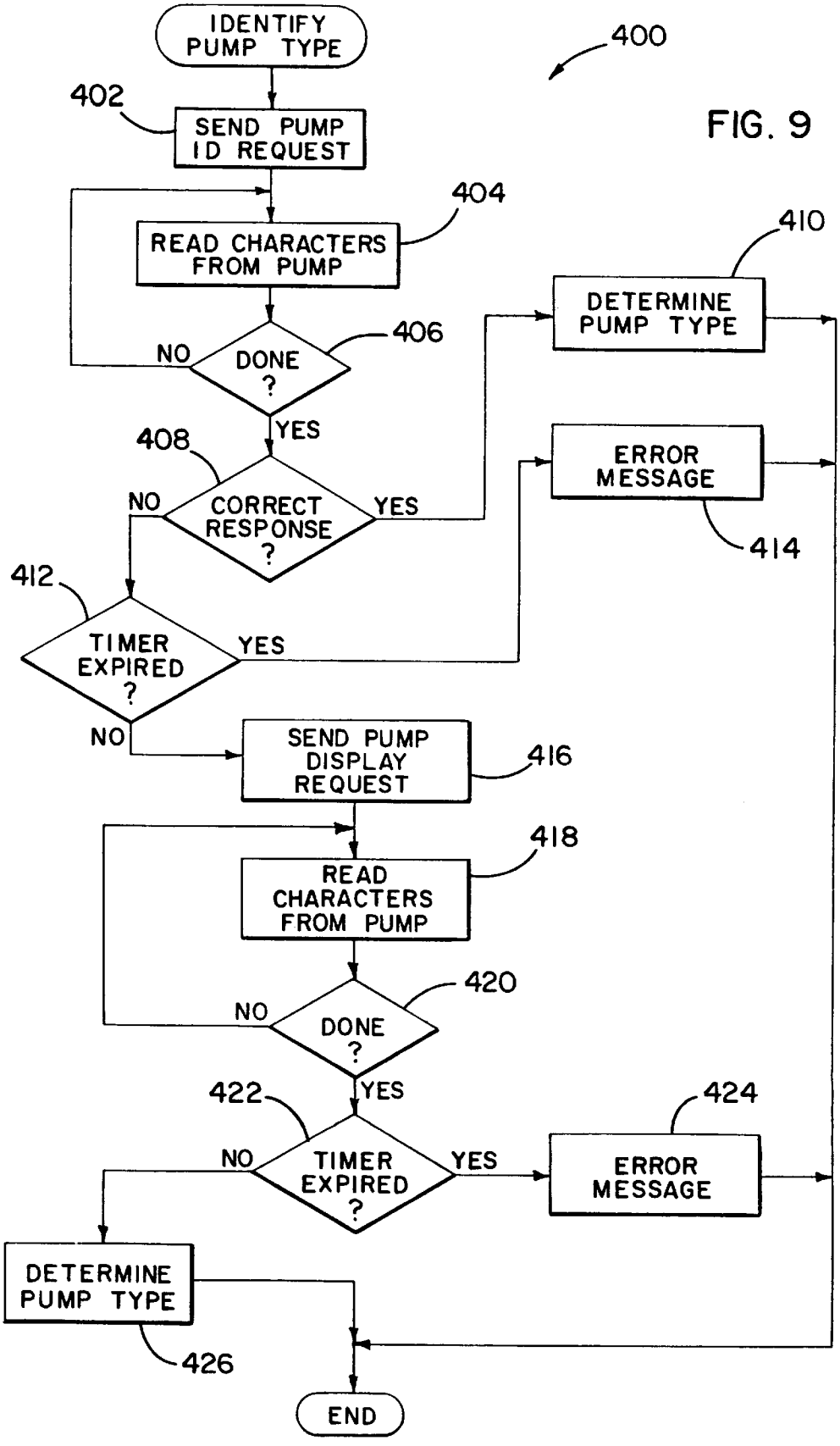

IDENTIFY PUMP TYPE
400
402
SEND PUMP ID REQUEST
404
READ CHARACTERS FROM PUMP
406
NO
DONE ?
YES
408
CORRECT RESPONSE ?
NO
YES
410
DETERMINE PUMP TYPE
ERROR MESSAGE
414
412
TIMER EXPIRED ?
YES
NO
SEND PUMP DISPLAY REQUEST
416
418
READ CHARACTERS FROM PUMP
420
NO
DONE ?
YES
422
TIMER EXPIRED ?
NO
YES
424
ERROR MESSAGE
DETERMINE PUMP TYPE
426
END

FIG. 9

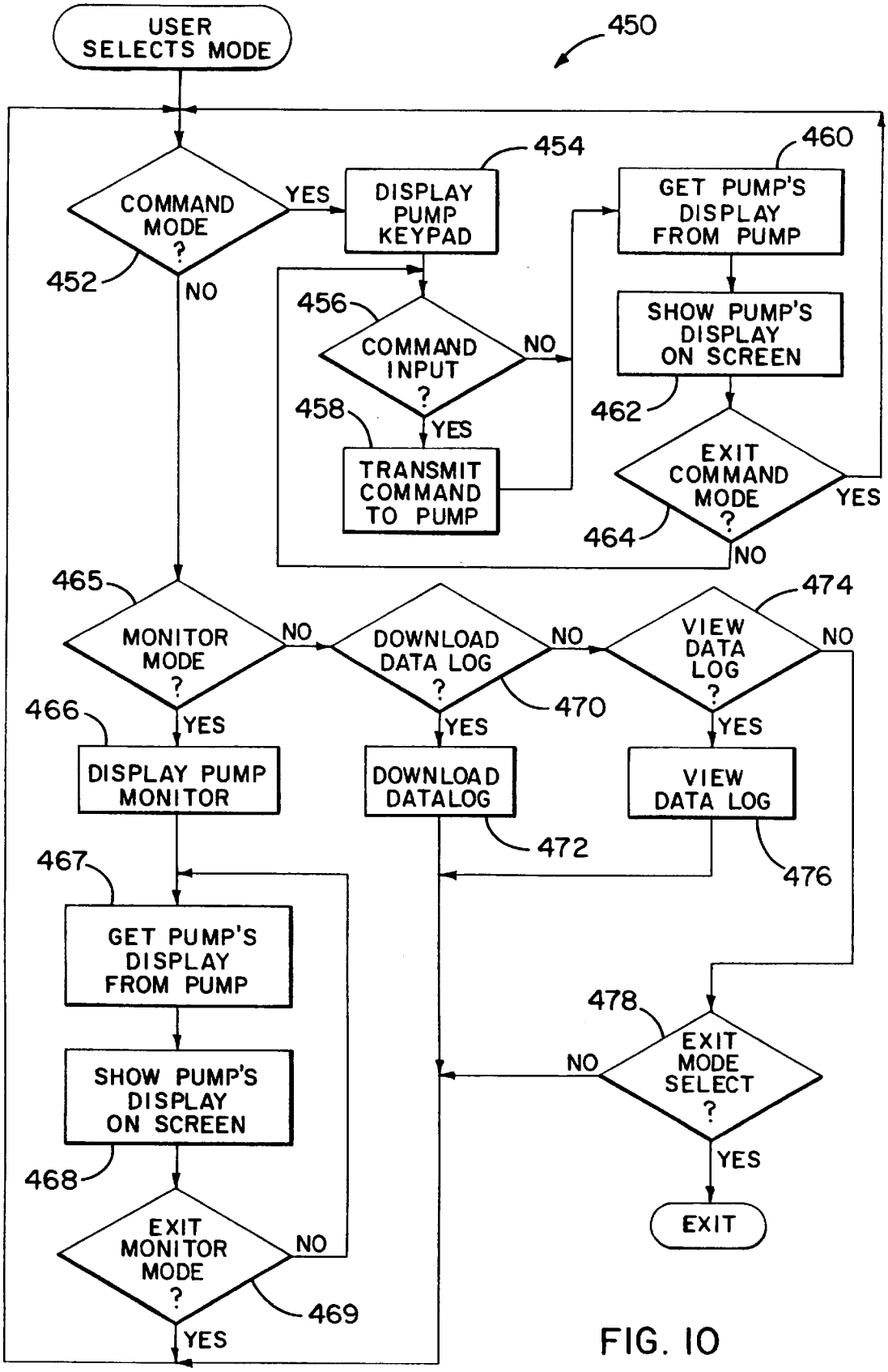

USER SELECTS MODE
450
COMMAND MODE ?
YES
NO
452
DISPLAY PUMP KEYPAD
454
COMMAND INPUT ?
456
NO
YES
458
TRANSMIT COMMAND TO PUMP
GET PUMP'S DISPLAY FROM PUMP
460
SHOW PUMP'S DISPLAY ON SCREEN
462
EXIT COMMAND MODE ?
464
YES
NO
MONITOR MODE ?
465
NO
DOWNLOAD DATA LOG ?
470
NO
VIEW DATA LOG ?
474
NO
YES
YES
YES
DISPLAY PUMP MONITOR
466
DOWNLOAD DATALOG
472
VIEW DATA LOG
476
GET PUMP'S DISPLAY FROM PUMP
467
SHOW PUMP'S DISPLAY ON SCREEN
468
EXIT MONITOR MODE ?
469
NO
YES
EXIT MODE SELECT ?
478
NO
YES
EXIT

FIG. 10

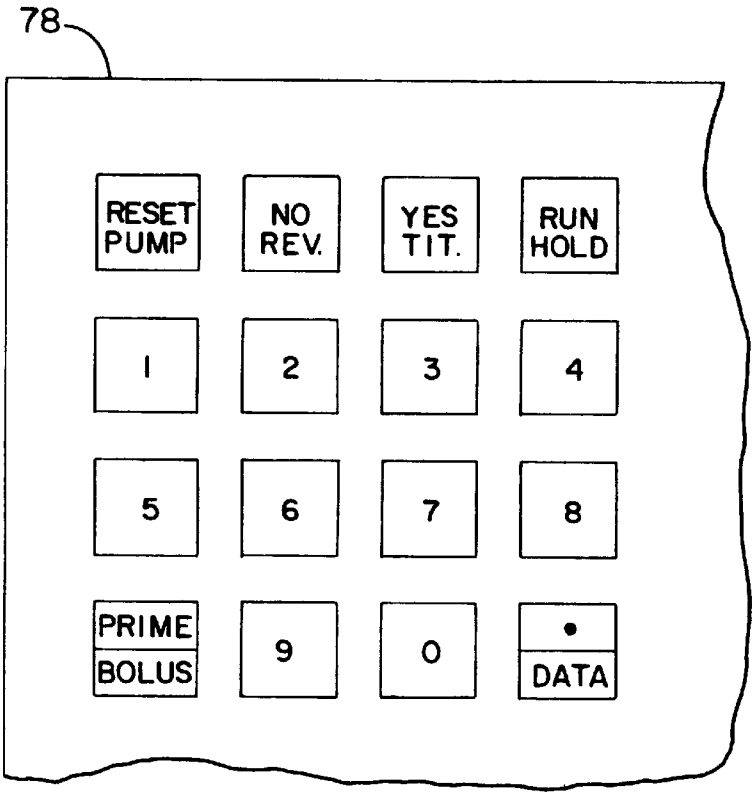


FIG. 11A

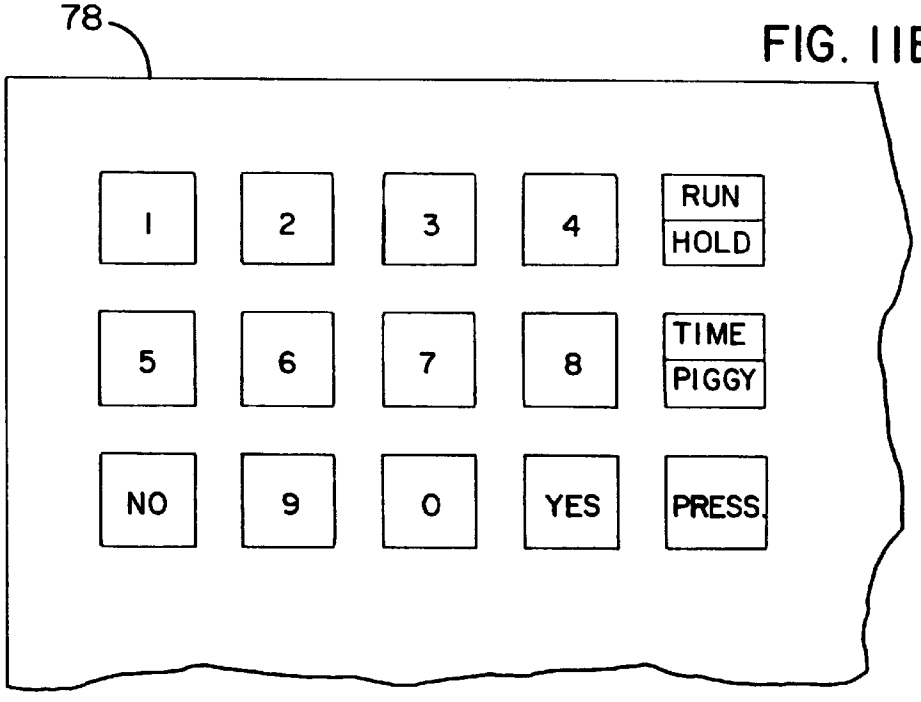


FIG. 11B

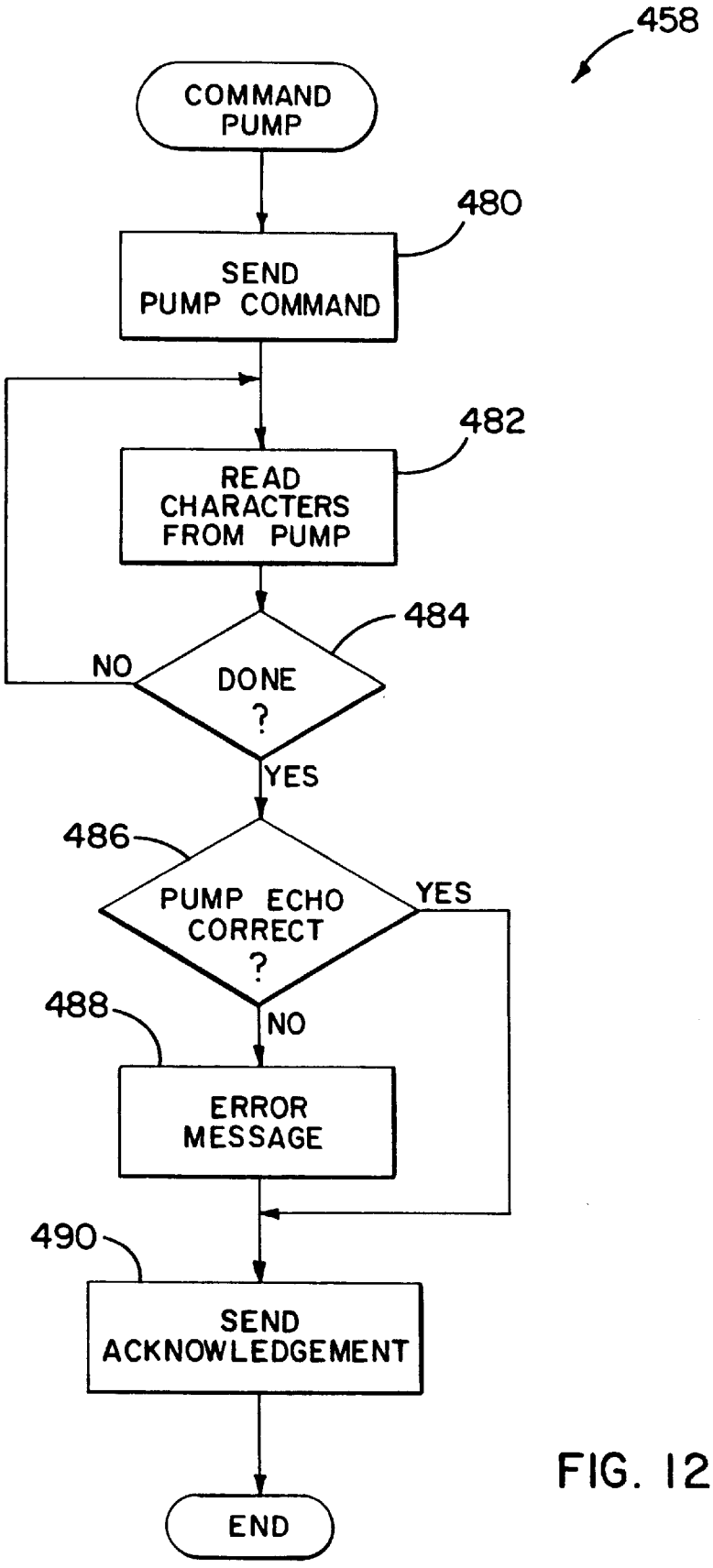

458
COMMAND PUMP
480
SEND PUMP COMMAND
482
READ CHARACTERS FROM PUMP
484
DONE ?
NO
YES
486
PUMP ECHO CORRECT ?
YES
NO
488
ERROR MESSAGE
490
SEND ACKNOWLEDGEMENT
END

FIG. 12

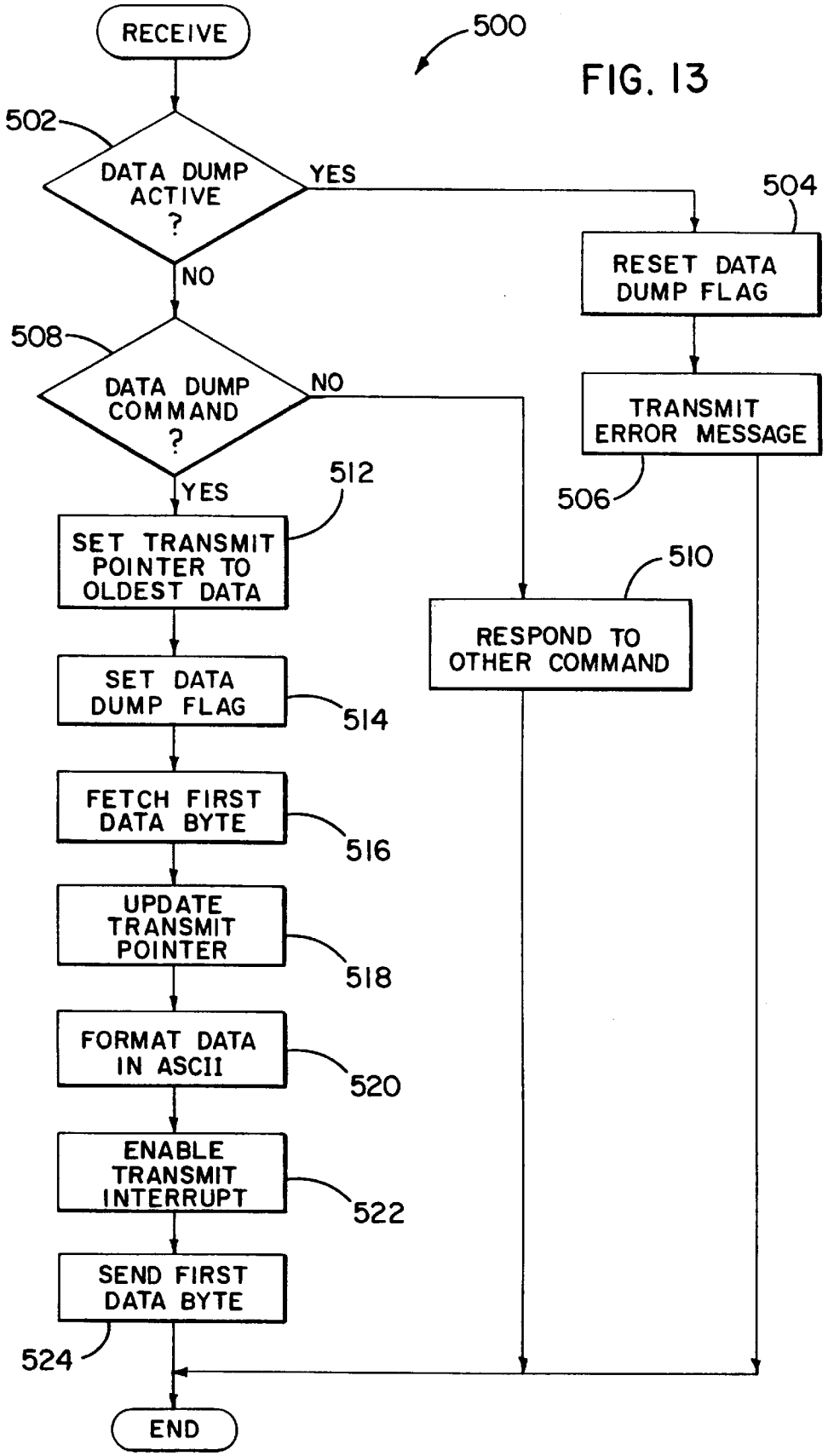

RECEIVE
500
502
DATA DUMP ACTIVE ?
YES
504
RESET DATA DUMP FLAG
NO
508
DATA DUMP COMMAND ?
NO
TRANSMIT ERROR MESSAGE
506
YES
512
SET TRANSMIT POINTER TO OLDEST DATA
510
RESPOND TO OTHER COMMAND
SET DATA DUMP FLAG
514
FETCH FIRST DATA BYTE
516
UPDATE TRANSMIT POINTER
518
FORMAT DATA IN ASCII
520
ENABLE TRANSMIT INTERRUPT
522
SEND FIRST DATA BYTE
524
END

FIG. 13

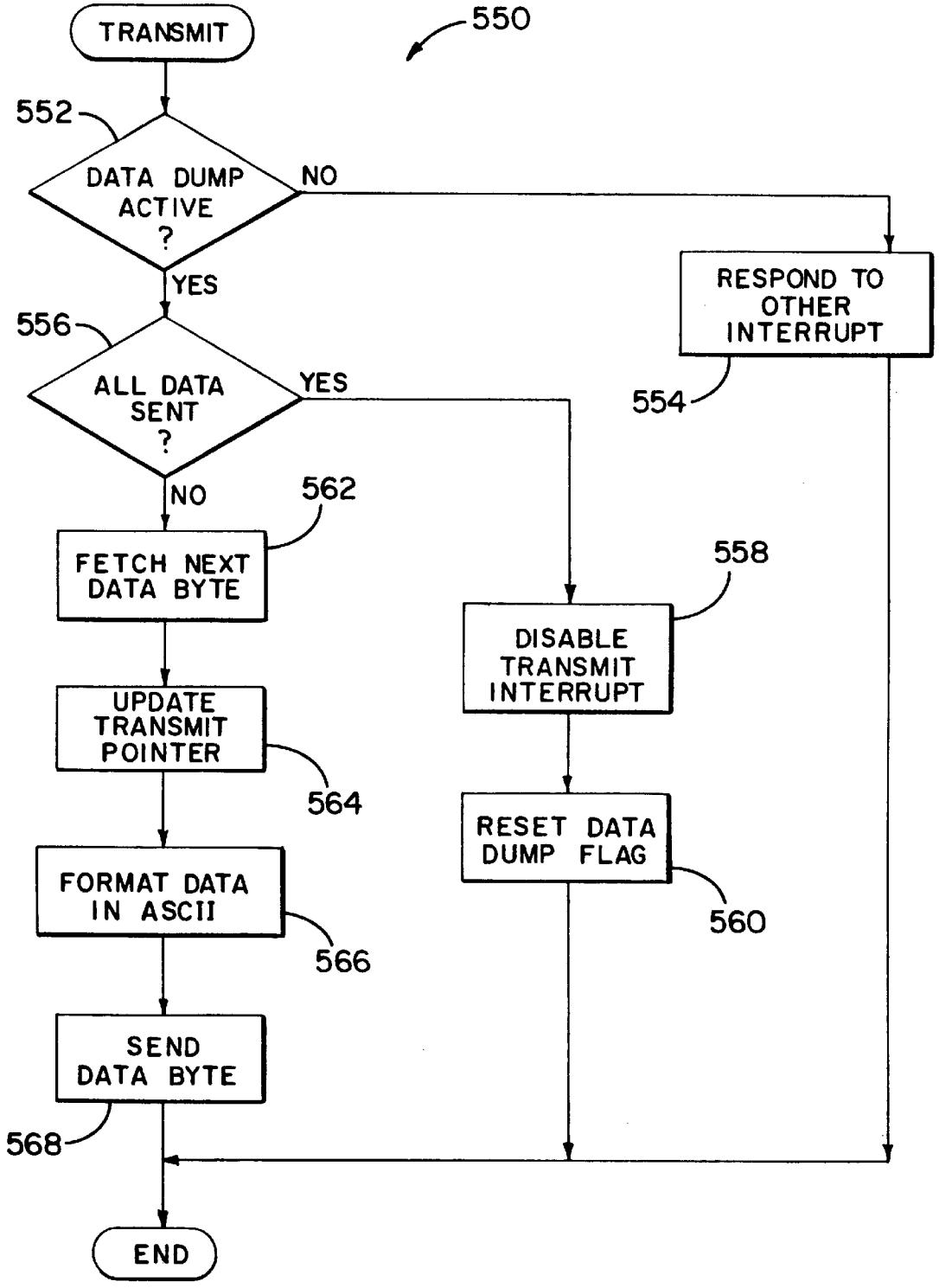

TRANSMIT
550
552
DATA DUMP ACTIVE ?
NO
YES
RESPOND TO OTHER INTERRUPT
554
556
ALL DATA SENT ?
YES
NO
562
FETCH NEXT DATA BYTE
558
DISABLE TRANSMIT INTERRUPT
UPDATE TRANSMIT POINTER
564
RESET DATA DUMP FLAG
560
FORMAT DATA IN ASCII
566
SEND DATA BYTE
568
END

FIG. 14

APPARATUS FOR MONITORING AND/OR CONTROLLING A MEDICAL DEVICE

This is a continuation of prior application Ser. No. 08/691,872, filed Aug. 2, 1996, now U.S. Pat. No. 5,807,336, which is hereby incorporated herein by reference in its entirety.

BACKGROUND OF THE INVENTION

The present invention is directed to an apparatus for monitoring and/or controlling a medical device, such as an infusion pump, from a remote location.

An infusion pump is used to automatically administer liquid medicant to a patient. The liquid medicant is supplied from a source of medicant and pumped into the patient via a catheter or other injection device. The manner in which the liquid is infused is controlled by the infusion pump, which may have various modes of infusion, such as a continuous mode in which the liquid medicant is continuously infused at a constant rate, or a ramp mode in which the rate of infusion gradually increases, then remains constant, and then gradually decreases.

Typically, the monitoring of an infusion pump is performed by reviewing a visual display means incorporated in the infusion pump, and the control of the infusion pump is performed by activating an input device, such as a keypad, incorporated with the infusion pump. Consequently, the monitoring and/or control of an infusion pump is performed at the same location at which the infusion pump is disposed.

SUMMARY OF THE INVENTION

The invention is generally directed to a medical apparatus having a programmable medical device disposed at a first room location and a remote monitor and/or controller disposed at a second room location.

In one aspect, the invention is directed to a medical apparatus having a medical device for administering a medical treatment to a patient, the medical device being disposed at a first room location and including means for administering the medical treatment to the patient and memory means for storing data regarding the medical treatment administered to the patient. The medical apparatus also includes a remote monitor for monitoring the medical treatment administered to the patient, the remote monitor being disposed at a second room location remote from the first room location, and means for transferring the data from the medical device to the remote monitor while the medical device is administering the medical treatment to the patient.

The data may be transmitted to the remote monitor in segmented, noncontinuous data portions, and the means for transferring the data to the remote monitor may include means for repeatedly transmitting portions of the data from the medical device to the remote monitor and means for generating an interrupt when one of the data portions has been transmitted to the remote monitor, the interrupt causing the transmitting means to transmit another of the data portions from the medical device to the remote monitor.

In a second aspect, the invention is directed to a medical apparatus having a medical device for administering a medical treatment to a patient, the medical device being disposed at a first room location and including means for administering the medical treatment to the patient and memory means for storing data regarding the medical treatment administered to the patient. The medical device also includes a remote monitor for monitoring the medical treatment administered to the patient, the remote monitor being disposed at a second room location remote from the first room location, a communication link operatively coupled between the medical device and the remote monitor, means for transferring the data from the medical device to the remote monitor via the communication link, and means for allowing voice communication between the medical device and the remote monitor via the communication link while the data is being transferred from the medical device to the remote monitor.

In a third aspect, the invention is directed to an apparatus having remote means for communicating with one of a plurality of medical devices each of which is designed to administer a medical treatment to a patient, the one medical device being disposed at a first room location and the remote means being disposed at a second room location remote from the first room location. The remote means includes means for automatically determining the type of the one programmable medical device and means for receiving data relating to the medical treatment of the patient after the type of the one programmable medical device has been determined. The apparatus also includes data communication means coupled to the remote means for transferring data between the remote means and the one programmable medical device.

The one programmable medical device may have a visual display device and the means for automatically determining the type of the one programmable medical device may include means for transmitting a display request to the one programmable medical device to request that the one programmable medical device transmit display data including a plurality of characters shown on the visual display device of the one programmable medical device, means for receiving the display data, and means for determining the type of the one programmable medical device based upon the display data.

The display data may include a number of characters and the determining means may include means for determining the type of the one programmable medical device based upon the number of characters in the display data. The means for automatically determining the type of the one programmable medical device may also include means of a first type for automatically determining the type of the one programmable medical device and means of a second type for automatically determining the type of the one programmable medical device.

These and other features and advantages of the present invention will be apparent to those of ordinary skill in the art in view of the detailed description of the preferred embodiment, which is made with reference to the drawings, a brief description of which is provided below.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a block diagram of an apparatus for administering medical treatment to a patient and monitoring the condition of the patient;

FIG. **2** is a block diagram of the electronic components of the remote monitor/controller shown schematically in FIG. **1**;

FIG. **3** is a front view of one embodiment of the infusion pump shown schematically in FIG. **1**;

FIG. **4** is a block diagram of the electronic components of the infusion pump of FIG. **3**;

FIG. **5** is a flowchart of the overall operation of the infusion pump;

FIG. **6** illustrates a number of data-recording steps performed during the operation of the infusion pump;

FIG. **7** is a representation of a portion of the memory of the infusion pump;

FIG. **8** is a flowchart of a store data routine which can be used to store data relating to the operation of the infusion pump and data relating to the condition of a patient;

FIG. **9** is a flowchart of a routine which may be used to identify the type of infusion pump to which the remote monitor/controller is coupled;

FIG. **10** is a flowchart of a mode select routine of the remote monitor/controller;

FIGS. **11A–11B** illustrate portions of visual displays generated by the remote monitor/controller;

FIG. **12** is a flowchart of a command pump routine that is performed by the remote monitor/controller;

FIG. **13** is a flowchart of a receive routine that is performed by the infusion pump;

FIG. **14** is a flowchart of a transmit routine that is performed by the infusion pump; and

FIG. **15** is an illustration of a graphical user menu that may be displayed by the remote monitor/controller.

DETAILED DESCRIPTION OF A PREFERRED EMBODIMENT

FIG. **1** illustrates one embodiment of an apparatus **10** for administering medical treatment to a patient. Referring to FIG. **1**, the apparatus **10** includes a programmable medical treatment means in the form of an infusion pump **12**, which is connected to a liquid medicant injection device in the form of a catheter **14** via a liquid conduit schematically shown as **16**.

The apparatus **10** includes a remote monitor/controller **20** which is disposed at a room location remote from the room location at which the infusion pump **12** is located. The remote monitor/controller **20** could be disposed in a different room of the same building in which the pump **12** is disposed, or in a different building than the one in which the pump **12** is disposed. The remote monitor/controller **20** is connected to a conventional voice/data modem **22** via a data link **24**, and the modem **22** is also connected to a telephone **26** via a voice link **28**. The infusion pump **12** is connected to a conventional voice/data modem **30** via a data link **32**, and the modem **30** is connected to a telephone **34** via a voice link **36**. The two modems **22**, **30** are interconnected to bidirectional voice and data communication via a communication link **38**, which could be a telephone line, for example.

FIG. **2** is a block diagram of the electronics of the remote monitor/controller **20** shown schematically in FIG. **1**. Referring to FIG. **2**, the remote monitor/controller **20** includes a microprocessor (MP) **60**, a read-only monitor (ROM) **62**, a random-access memory (RAM) **64**, and an input/output (I/O) circuit **66**, all of which are interconnected by an address/data bus **68**. The microprocessor **60** has a transmit buffer (XMIT) **70** for transmitting data bytes and a receive buffer (REC) **72** for receiving data bytes. The remote monitor/controller **20** has a keyboard **74** connected to the I/O circuit **66** via a line **76**, a display device **78**, such as a CRT, connected to the I/O circuit **66** via a line **80**, and an input device, such as an electronic mouse **82**, connected to the I/O circuit **66** via a line **84**. The remote monitor/controller **20** can also include one or more disk drives, such as a hard disk drive or a floppy disk drive.

FIG. **3** is a front view of one embodiment of the infusion pump **12** shown schematically in FIG. **1**. Referring to FIG. **3**, the pump **12** has an input device in the form of a keypad **90** via which a user may input data and commands and a display **92** for displaying textual messages to the user.

A block diagram of the electronics of the infusion pump **12** is shown in FIG. **4**. Referring to FIG. **4**, the pump **12** includes a controller **100**, an electrically programmable read-only memory (EPROM) **102** having a built-in I/O interface **102***a*, a nonvolatile RAM **104**, a real-time clock **106** and the display **92**, all of which are interconnected by a communications bus **108**. The display **92** has a backlight **110** which is selectively activated by an enable signal generated on a line **112** interconnecting the controller **100** and the backlight **110**. Both the RAM **104** and the real-time clock **106** are connected to a battery **114** which supplies power to them only in the absence of system power. The controller **100** has a transmit buffer **116** and a receive buffer **118** connected to the communications bus **108**.

The controller **100** controls the medicant infusion rate by periodically transmitting a control signal to an amplifier circuit **120** via a line **122** to drive a pump motor **124** which drives a pumping mechanism **126**, such as a rotary pump wheel (not shown) adapted to make contact with a portion of the liquid conduit **16** (FIG. **1**) connected to the catheter **14**.

The controller **100** receives periodic inputs from a shaft encoder (SE) sensor **130**, which is disposed on the shaft of the motor **124**. The SE sensor **130** may be a two-phase motion sensing encoder which provides two signal outputs to the controller **100**. The rotational speed of the motor **124** and its direction of rotation are determined by the controller **100** based upon the rate and phase relationship between the two signal outputs.

The SE encoder **130** periodically transmits the signals to the controller **100** via a line **132**. Each time the signals are transmitted, an interrupt is generated, and the controller **100** compares the actual position of the motor shaft with its desired position, and transmits a new control signal, such as a pulse-width modulated signal, to the amplifier **120** via the line **122** to ensure that the actual speed of the motor **124** corresponds to the motor speed required for the desired medicant infusion rate. The interrupts caused by the SE sensor **130** are assigned to the highest priority so that they are responded to immediately, before any other actions are taken by the controller **100**.

The pump **12** has a number of other features not described herein, which are disclosed in the following patent applications, each of which is incorporated herein by reference; U.S. Ser. No. 08/399,184, filed Mar. 6, 1995, entitled "Infusion Pump Having Power Saving Modes"; U.S. Ser. No. 08/398,977, filed Mar. 6, 1995, entitled "Infusion Pump With Selective Backlight"; U.S. Ser. No. 08/398,980, filed Mar. 6, 1995, entitled "Infusion Pump With Different Operating Modes"; U.S. Ser. No. 08/398,886, filed Mar. 6, 1995, entitled "Cassette For An Infusion Pump; U.S. Ser. No. 08/399,183, filed Mar. 6, 1995, entitled "Infusion Pump With Dual-Latching Mechanism"; U.S. Ser. No. 08/398,887, filed Mar. 6, 1995, entitled "Infusion Pump With Historical Data Recording."

The operation of the infusion pump **12** is controlled by a computer program stored in the EPROM **104** and executed by the controller **100**. A flowchart **200** of the overall operation is illustrated in FIG. **5**. Referring to FIG. **5**, when the pump **12** is turned on, at step **202** the pump is initialized and a test of the pump operation is performed. The pump **12** may be turned off temporarily during an infusion, in which case the pump **12** may continue the infusion when it is turned back on, as described below. At step **204**, if there is any

remaining volume of liquid to be infused by the pump or any additional time remaining for an infusion, which would be the case where the pump was temporarily turned off during an infusion, the program branches to step **206**, where the user is asked, via a message displayed on the display **92**, whether the previous infusion should be resumed. If the user answers yes (via the keypad **90**), the program branches to a ready-to-run step **210**. If the previous infusion is not to be resumed, the program branches to step **212**.

The infusion pump **12** has a lockout mode in which the user may be prevented from programming the infusion parameters, such as the volume to be infused or the rate of infusion. For example, the pump **12** could be programmed by a medical assistant to deliver a particular infusion having a particular flow profile, flow rate and volume to be infused. After programming that infusion, the medical assistant could place the pump in lockout mode, which would prevent the patient from changing any of the infusion parameters. At step **212**, if the pump **12** has been previously placed in lockout mode, the program branches directly to the ready-to-run step **210**, bypassing all programming steps.

At step **212**, if the pump is not in lockout mode, the program branches to step **214**, at which point the program prompts the user, via the display **92**, to input whether the patient should be allowed to program the pump during the subsequent infusion. If the pump is not to be programmable, the program branches to step **216** where a lockout sequence is performed by requesting the user to input which infusion modes should be locked out. If the pump is to be programmable by the patient, the program bypasses step **216**.

The infusion pump **12** has five basic modes of infusion: 1) a continuous mode in which the pump delivers a single volume at a single rate; 2) an auto-ramp mode in which the pump delivers liquid at a rate that gradually increases to a threshold rate, stays constant at the threshold rate, and then gradually decreases; 3) an intermittent mode in which the pump delivers discrete liquid volumes spaced over relatively long periods of time, such as a liquid volume every three hours; 4) a custom mode in which the pump can be programmed to deliver a unique fusion rate during each of 25 different time periods; and 5) a pain-controlled analgesic (PCA) mode during which the pump will periodically infuse boluses of analgesic in response to periodic requests by the patient.

At step **218**, the pump **12** generates on the display **92** the prompt "Continuous?" to the user. If the user desires to use the pump in its continuous mode, the user answers "yes" via the keypad **90**, and the program branches to step **220** at which the continuous mode is programmed by the user by entering a number of infusion parameters, such as the desired infusion rate, the volume to be infused, etc. At step **218**, if the user does not want to use the continuous mode, the user answers "No," and the program branches to step **222**. Steps **222–236** are generally the same as steps **218** and **220**, except that the user may be prompted for different infusion parameters, depending on which of the five possible infusion modes is selected.

After the completion of one of the steps **220**, **224**, **228**, **232**, or **236**, the program branches to the ready-to-run step **210**. When the user presses the "Run" key, the pump **12** enters the run mode **260** and infuses the patient with a liquid medicant in accordance with the infusion mode selected at one of steps **218**, **222**, **226**, **230**, **234** and the infusion parameters entered at one of steps **220**, **224**, **228**, **232**, **236**. The pump **12** remains in the run mode **260** until the "Hold" key is pressed, as determined at step **262**. Upon the occurrence of an alarm condition, an alarm is reported at step **264**. At step **262**, if the hold key is pressed, the infusion is stopped at step **266**, and the pump **12** waits for the run key to be pressed at step **268** or the on/off switch to be turned off at step **270**.

Summarizing the operation described above, if the pump is to be utilized in lockout mode, a medical assistant turns the pump on, programs the desired infusion mode at one of steps **220**, **224**, **228**, **232**, **236**, and then turns the pump off. The programmed infusion parameters will be retained in the memory **104**. The medical assistant would then turn the pump back on, press the "No" key in response to the "Programmable?" prompt at step **214**, enter the lockout information at step **216**, and then turn the pump off again. When the patient subsequently turned on the pump to perform the infusion, the program would proceed from step **212** directly to the ready-to-run step **210**, which could prevent the patient from altering the infusion parameters.

If the lockout mode was not utilized, the medical assistant or the patient could turn the pump on, program the desired infusion mode, and then press the "Run" key to start the infusion without ever turning the pump off.

During programming and operation, the infusion pump **12** automatically records in the non-volatile memory **104** all significant infusion data to generate a complete historical data record which can be later retrieved from the memory **104** and used for various purposes, including clinical purposes to aid in determining how effective a particular infusion therapy was and treatment purposes to confirm that the prescribed infusion was actually delivered.

FIG. **6** illustrates various steps at which infusion data is recorded that are performed during the overall pump operation shown generally in FIG. **5**. The infusion data recorded in the memory **104** is set forth in Table 1 below. A number of events which trigger the storage of data are listed in the left-hand column of Table 1, and the infusion data that is recorded upon the occurrence of each event is listed in the right-hand column of Table 1. The time at which the infusion data is recorded, which is determined by the real-time clock **106**, is also stored along with the infusion data.

TABLE 1

EVENT	DATA RECORDED
Power On	Date and Time
Program	Infusion parameters. See Table 2.
Run	Infusion parameters. See Table 2.
Hold	Total Volume Infused
Restart	Time of Restart
Rate Changes	Total Volume Infused, Rate, Volume
Alarms	Total Volume Infused, Alarm Type
Infusion Complete	Total Volume infused
Malfunctions	Total Volume Infused, Malfunction Type
Resume	Infusion parameters. See Table 2.
Maintenance Date	Date
Patient ID	Patient ID Number
Serial No.	Serial Number
Language Change	New Language
Lockout	Modes Locked Out
Pressure Select	New Pressure Setting
Bolus Request	Given/Not Given, Bolus Amount
Titration	New Parameters
Power Off	Time of Power Off
Version No.	Software Version Number

Referring to Table 1 and FIG. **6**, when the power to the infusion pump **12** is turned on, the date and time of the power turn-on is recorded. When the pump is completely programmed pursuant to one of steps **220**, **224**, **228**, **232**,

236 (FIG. 5) as determined at step 302, the programmed infusion parameters are stored at step 304, along with the time of such storage. The particular parameters that are stored depend upon which infusion mode was programmed. Several examples of infusion parameters that are stored for each of a number of infusion modes are illustrated in Table 2 set forth below.

TABLE 2

INFUSION MODE	INFUSION PARAMETERS
Continuous	Infusion Mode
	Infusion Rate
	Volume To Be Infused
	Delay Time
	Total Bag Volume
	KVO Rate
Auto-Ramp	Infusion Mode
	Infusion Rate
	Volume To Be Infused
	Delay Time
	Total Bag Volume
	Duration of Up-Ramp
	Duration of Down-Ramp
	KVO Rate
Intermittent	Infusion Mode
	Total Infusion Time
	Number of Doses
	Dose Time
	Dose Volume
	KVO Rate

When the pump enters the run mode 260 (FIG. 5) as determined at step 306, the time at which the run mode was begun, along with the parameters pursuant to which the infusion is performed, are stored at step 308.

At step 310, if the hold key is pressed, then the time at which the hold key was pressed along with the total volume infused at the time the hold key was pressed are stored at step 312. The pump also stores any infusion rate changes, such as changes caused by switching from a continuous rate to a keep-vein-open (KVO) rate, or in the intermittent mode, changing from a KVO rate to a higher infusion rate, the presence of which are detected at step 314. The new rate and the time at which the new rate started are stored at step 316.

At step 318, if any alarms are generated, the alarm type, the time at which the alarm occurred, and the total volume infused at the time of the alarm are recorded at step 320. If the infusion is completed as determined at step 322, the program branches to step 324 where the time at which the infusion was completed is stored along with the total volume infused. At step 326, if there is a malfunction, the malfunction type, the time at which the malfunction occurred, and the total volume infused at the time of the malfunction are recorded at step 328.

At step 330, if the infusion is resumed (when the pump is turned back on after having been turned off during an infusion), the time at which the infusion is resumed along with the infusion parameters are stored at step 332. Upon the completion of the programming of a lockout sequence as determined at step 334 (i.e. after step 216 of FIG. 5), the time at which the programming of the lockout was completed is stored along with the infusion modes that were locked out. At step 338, upon the detection of a bolus request, the time at which the bolus was requested is stored at step 340, along with an indication whether the bolus was actually given and the amount of the bolus.

FIG. 7 illustrates the data organization of a portion of the RAM 104 in which infusion data (the data stored during the steps of FIG. 6) is stored. Referring to FIG. 7, the infusion data is stored in a number of memory locations 372. Data may be written to the memory location 372 utilizing a pointer 376 which specifies the memory location at which data should be next stored.

FIG. 8 is a flowchart of a routine 380 for storing data in the memory locations 372. Referring to FIG. 8, at step 382 the pointer 376 is set to the address of the next memory location 372 in which data is to be stored. At step 384, if the pointer 376 is at the last memory location in which data may be stored, the routine branches to step 386 where the pointer is set to the address of the first memory location in which data may be stored. As a consequence of steps 384, 386, the contents of the memory locations 372 are periodically overwritten with new data; however, the number of memory locations 372 is sufficiently large so that several months of data, for example, is stored before being overwritten. At steps 388 and 390 the data is stored in the memory location 372 specified by the pointer 376 (the data includes a time stamp generated from the real-time clock 106 and event data specifying the particular infusion event).

FIGS. 9, 10, and 12 are flowcharts of various routines that are performed by the remote monitor/controller 20. As described in more detail below, the remote monitor/controller 20 may be used to monitor the operation of the infusion pump 12, to control the operation of the infusion pump 12, and/or to transfer infusion data and patient data from the infusion pump 12 so that such data can be reviewed by a health care professional at a location remote from the patient.

The remote monitor/controller 20 is designed to interface with different types of infusion pumps. In order to determine which type of infusion pump the remote monitor/controller 20 is operatively coupled, a pump identification routine 400 performed after the communication link between the remote monitor/controller 20 and the infusion pump 12 is established. Referring to FIG. 9, at step 402 the remote monitor/controller 20 transmits a pump identification (ID) request to the infusion pump 12 via the communication link 38. In response to the pump ID request, the pump 12 transmits a multi-character ID code back to the remote monitor/controller 20. The ID code may include, for example, one or more characters identifying the pump model and/or one or more characters identifying the software version of the pump. At step 404, the remote monitor/controller 20 reads the characters sent from the pump 12 until all characters are received as determined at step 406 or until a predetermined time period, e.g. five seconds, elapses. The time period may be determined by a timer (not shown). The remote monitor/controller 20 may determine that all characters have been received by, for example, identifying one or more termination characters, such as a carriage-return character <CR> followed by a line-feed character <LF>.

Step 408 determines whether a correct response was received from the pump 12, which may be determined checking the characters received from the pump 12 against a list of possible ID codes. If a correct response was received, the routine branches to step 410 where the pump type is determined for example, by comparing the received pump ID code with at least one possible ID code which identifies a particular type of infusion pump, or by comparing the received pump ID code with a number of possible ID codes, each of which identifies a particular type of infusion pump. As used herein, the "type" of infusion pump may relate to the model of the pump or the software version of the pump.

If a correct response was not received as determined by step 408, at step 412 the routine determines whether the predetermined time period measured by the timer has

expired prior to receiving a termination character. If so, the routine branches to step **414** where an error message is generated due to the pump's failure to respond to the pump ID request.

At step **412**, if some type of response (not a correct response) was received before the timer expired, the routine branches to step **416**. Steps **416–426** comprise a second way of determining the type of infusion pump **12** connected to the remote monitor/controller **20**, which is based on the number of characters in the display **92** of the pump **12**. For example, a first type of infusion pump may have a display capable of displaying 12 characters, whereas a second type of infusion pump may have a display capable of displaying 12 characters. Steps **416–426** determine the type of infusion pump based on the number of characters in the display.

At step **416**, the remote monitor/controller **20** transmits a pump display request to the infusion pump **12** to request the pump **12** to transmit the content of its display **92**. At step **418**, the remote monitor/controller **20** reads the display characters transmitted from the pump **12**. At step **420**, if a predetermined period of time has elapsed or if a terminating character is received, the routine branches to step **422**. At step **422**, if the predetermined time period measured by the timer elapsed prior to the receipt of a terminating character, the routine branches to step **424** where an appropriate error message is generated. At step **426**, the type of pump is determined based on the number of display characters that were received.

The routine could also exit step **420** if a predetermined number of characters are received. In that case, where the remote monitor/controller **20** was designed to interface with two different types of infusion pumps, one having a display capability of 12 characters and another having a display capability of 32 characters, if the remote monitor/controller **20** received more than 12 display characters at step **420**, it would immediately be able to determine that the pump type corresponded to a pump with a 32-character display capability.

The remote monitor/controller **20** allows four basic functions to be performed, including controlling the infusion pump **12**, monitoring the operation of the pump **12**, transferring infusion data from the pump **12** to the remote monitor/controller **20**, and viewing the data. The user may perform one of those functions by selecting an operational mode displayed on the display device **78** (FIG. **2**) of the remote monitor/controller **20** via the mouse **82**. These modes include a command mode in which a health care professional at the remote monitor/controller **20** may transmit command signals to the infusion pump **12** to control its operation, a monitoring mode in which the infusion pump **12** will continually transmit the contents of its visual display **92** to the remote monitor/controller **20**, a download data mode in which infusion data is transferred from the pump **12** to the remote monitor/controller **20**, and a view data mode in which the infusion data may be viewed on the display **78** of the remote monitor/controller **20**.

FIG. **10** illustrates a flowchart **450** of the basic operation of the remote monitor/controller **20**. Referring to FIG. **10**, at step **452**, if the user selected the command mode described above, the routine branches to step **454** where a display of the keypad **90** of the infusion pump **12** is shown on the display device **78**. The display shown at step **454** comprises a plurality of virtual entry keys having a spatial configuration substantially the same as the entry keys of the keypad **90** of the particular infusion pump type which is connected to the remote monitor/controller **20**. An example of such a visual display is shown in FIG. **11**A.

It should be noted that the virtual keypad shown in FIG. **11**A is the same as the actual keypad **90** of the pump **12**, which is shown in FIG. **3** (except that the on/off key of the pump **12** is replaced with a reset key in the virtual key display). Where a different type of pump having a different keypad is attached to the remote monitor/controller **20**, that particular keypad is displayed on the display device **78**. An example of a different virtual keypad is shown in FIG. **11**B. Various virtual keypad configurations may be stored in the memory of the remote monitor/controller **20**, each virtual keypad configuration having a pump type code associated therewith. Since the remote monitor/controller **20** initially determined the type of pump to which it was attached (via the routine of FIG. **9**), it can retrieve from memory and display the corresponding virtual keypad for that type of pump.

After the virtual keypad is displayed, the health care professional may control the operation of the infusion pump **12** by selecting any of the virtual keys with the mouse **82**. Other ways of selecting the keys could be utilized, such as a touch-sensitive screen or a display screen activated by radiation sensors. The infusion pump **12** responds to commands entered via its keypad **90** and to commands generated from the remote monitor/controller **20**. At steps **456** and **458**, any commands entered by the health care professional are transmitted to the infusion pump **12**, and at steps **460** and **462**, the display of the pump **12** is transferred to the remote monitor/controller **20** and displayed on the display device **78** of the remote monitor/controller **20**. At step **464**, if the user exits the command mode, the routine branches back to step **452**.

At step **465**, if the health care professional selected the monitor mode, the routine branches to step **466** where a visual display of the pump display **92** is shown on the display device **78**. At step **467**, the contents of the pump display **92** are transferred to the remote monitor/controller **20**, and at step **468** those contents are displayed in the visual display generated at step **466**. At step **469**, if the user exits the monitor mode, the routine branches back to step **452**; otherwise, the routine branches back to step **467** so that the contents of the pump display **92** are continuously shown on the display device **78** at step **468** (the display **92** of the infusion pump **12** changes in accordance with the pump operation so that the pump operation can be monitored by viewing the display **92**). Step **467** may be accomplished, for example, by transmitting a pump display request to the pump **12** (via steps similar to steps **416–420** described above).

If the health care professional inputs a request to download data from the pump **12** to the remote monitor/controller **20** as determined at step **470**, the routine branches to step **472** where the data transfer is accomplished, as described below in connection with FIGS. **13–14**. If the user inputs a view data log request as determined at step **474**, the routine branches to step **476** where data previously downloaded at step **472** can be viewed on the display device **78** of the remote monitor/controller **20**. The user may exit the mode select routine **450** via step **478**.

FIG. **12** illustrates one routine that could be used to implement the transmit command step **458** shown schematically in FIG. **10**. Referring to FIG. **12**, the pump command is transmitted from the remote monitor/controller **20** at step **480**, and then the infusion pump **12** transmits to the remote monitor/controller **20** an echo of the command so that the remote monitor/controller **20** known that command was received properly by the pump **21**. The characters making up the echo are received at steps **482–484**, and if the echo is not

correct, an error message is displayed to the health care professional. At step **490**, the remote monitor/controller **20** sends an acknowledgement of the echo to the pump **12**.

The transfer of data from the infusion pump **12** to the remote monitor/controller **20** shown schematically in step **468** of FIG. **10** is accomplished via a receive interrupt service routine **500** and a transmit interrupt service routine **550** that are performed by the infusion pump **12**. Flowcharts of the routines **500**, **550** are shown in FIGS. **13** and **14**.

The receive routine **500** shown in FIG. **13** is invoked upon the generation of a receive interrupt by the pump controller **100**. The receive interrupt indicates that a message has been received in the receive buffer **118** of the controller **100** from the remote monitor/controller **20**. When a download data command is sent to the infusion pump **12** (as determined at step **466** of FIG. **10**), a data dump flag is set to logic "1" indicating that a data transfer or dump from the pump **12** to the remote monitor/controller **20** is in progress. The data transfer is performed in a segmented fashion. Instead of sending all of the infusion data and patient data stored in the RAM **104** to the remote monitor/controller **20** in a single, continuous stream, the data is sent in segmented portions, each of which is separated in time from its adjacent portions by a period of time, e.g. 100 microseconds.

Referring to FIG. **13**, when the routine begins at step **502**, a character or message will have been just received in the receive buffer **118**. At step **502**, if the data dump flag is active, meaning that a data transfer is already in progress, then the routine branches to step **504**, where the data dump flag is set to logic "0", effectively terminating the data dump operation, and an error message is transmitted to the remote monitor/controller **20** at step **506**. This is done to prevent the data dump operation from interfering with any commands that are transmitted from the remote monitor/controller **20** to the infusion pump **12**.

If the data dump flag was not active as determined at step **502**, the routine branches to step **508** where the message just received in the receive buffer **118** is checked to determine whether it is a data dump command. If it is not, then the routine branches to step **510** where the pump **12** responds to the command.

If the message is a data dump command, the routine branches to step **512** where a transmit pointer **513** (see FIG. **7**) is set to the oldest data in the RAM **104** that has not yet been transmitted to the remote monitor/controller **20**. At step **514**, the data dump flag is set to logic "1" since a new data transfer operation is beginning. At step **516**, the data byte specified by the transmit pointer **513** is retrieved from the RAM **104**, and at step **518** the position of the transmit pointer **513** is updated (e.g. incremented) to point to the address of the next data byte to be transmitted. At step **520**, the data byte retrieved at step **516** is formatted in ASCII; at step **522** the transmit interrupt is enabled; and at step **524** the reformatted data byte is transmitted from the infusion pump transmit buffer **116** to the remote monitor/controller **20** over the data link **38**.

When the first data byte is sent out from the transmit buffer **116**, a transmit interrupt is generated by the controller **100** to indicate that the transmit buffer **116** is empty and that another data byte can be transmitted. Upon the generation of the transmit interrupt, the transmit routine **550** is performed. Referring to FIG. **14**, at step **552** the status of the data dump flag is checked. If the flag is not active, meaning that a data dump operation is not in progress, the routine branches to step **554** where the routine responds to the other interrupt. If the data dump flag is active, then the routine branches to step **556**, where it determines whether all of the segmented portions of the infusion data have been transmitted. This may be accomplished, for example, by determining if the transmit pointer **513** and the pointer **376** (FIG. **7**) are pointing to the same memory location. If all the requested data has been sent, the routine branches to step **558**, where the transmit interrupt is disabled, and then to step **560** where the data dump flag is reset to logic "0," effectively ending the data transfer operation.

If not all the data has been transferred as determined at step **556**, the routine branches to step **562** where the data byte specified by the transmit pointer **513** is retrieved from the RAM **104**. At step **564** the position of the transmit pointer is updated to point to the address of the next data byte to be transmitted. At step **566**, the data byte retrieved at step **562** is formatted in ASCII, and at step **568** the reformatted data byte is transmitted from the infusion pump transmit buffer **116** to the remote monitor/controller **20** over the data link **38**.

The transmit interrupts generated by the controller **100** to transfer the segmented data portions to the remote monitor/controller **20** are assigned a lower priority than the interrupts generated in response to input of the shaft encoder sensor **130**, which is necessary to provide the desired infusion rate. Consequently, the transfer of the infusion data and patient data does not interfere with the ability of the pump **12** to provide the desired infusion rate, and the data transfer can occur while the pump is infusing the patient with the medicant.

FIG. **15** is an illustration of a graphical user menu that may be shown on the display device **78** of the remote monitor/controller **20**. The health care professional may select particular data for transfer or viewing, via a number of different parameters such as beginning data, ending data, types of data, etc. The particular manner in which particular data may be selected for transfer or viewing is not considered important to the invention.

Modifications and alternative embodiments of the invention will be apparent to those skilled in the art in view of the foregoing description. This description is to be construed as illustrative only, and is for the purpose of teaching those skilled in the art the best mode of carrying out the invention. The details of the structure and method may be varied substantially without departing from the spirit of the invention, and the exclusive use of all modifications which come within the scope of the appended claims is reserved.

What is claimed is:

1. A medical apparatus, comprising:

a medical device for interacting with a patient, disposed at a first location;

a remote apparatus for monitoring and/or controlling the medical device, the remote apparatus being disposed at a second location remote from the first location;

a communication link operatively coupled between the medical device and the remote apparatus;

apparatus for transferring data and/or commands between the medical device and the remote apparatus via the communication link; and

apparatus for providing voice communication between the medical device and the remote monitor/controller via the communication link contemporaneously while data and/or commands are being transferred between the medical device and the remote monitor/controller.

2. The medical apparatus of claim **1** wherein the remote apparatus comprises a routine for programming the medical device and a routine for monitoring the medical device.

3. The medical apparatus of claim **1** wherein the medical device comprises a device for administering a medical treatment to a patient.

4. The medical apparatus of claim 1 wherein the medical device comprises a device for monitoring a medical condition of the patient.

5. The medical apparatus of claim 2 wherein the medical device comprises a memory for storing data regarding the medical device's interaction with the patient and operation of the medical device and wherein the remote apparatus comprises a routine for downloading data stored in the medical device and a routine for viewing data from the medical device.

6. The medical apparatus of claim 1 wherein the medical device comprises a controller for controlling the interaction of the medical device with the patient.

7. The medical apparatus of claim 1 wherein the apparatus for allowing voice communication comprises:

a first voice/data modem operatively coupled to the medical device; and

a second voice/data modem operatively coupled to the remote apparatus, the first and second voice/data modems being coupled to the communication link.

8. The medical apparatus of claim 1 wherein the communication link comprises a telephone line.

9. The medical apparatus of claim 1 wherein the medical device comprises a programmable infusion pump.

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